

Special 510(k): Device Modification Summary
NovaBone Porous – Bone Graft Scaffold

03/16/09

1. Submitter Information:

Name: NovaBone Products, LLC
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Alachua, FL 32615
Telephone: (386) 462-7660
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Contact: David M. Gaisser

2. Name of Device:

Trade Name: NovaBone Porous – Synthetic Bone Graft Scaffold
Common Name: Osteoconductive Bone Void Filler
Synthetic Resorbable Bone Graft Material
Regulation Number: 21 CFR 888.3045
Regulation Name: Bone Void Filler

3. Legally Marketed Predicate Device:

Predicate #1: NovaBone Porous – Bone Graft Scaffold
[K060432]]
Predicate #2: NovaBone Putty – Bioactive Synthetic Graft
[K060728, K080009, K082672]
Predicate #3: NovaBone-AR – Resorbable Bone Graft Substitute
[K041613]

4. Device Description

NovaBone Porous is an osteoconductive bioactive device. It is a one-component, resorbable bone void filler composed of a synthetic calcium phospho-silicate (Bioglass) particulate, fused into a bulk porous form having a multidirectional interconnected porosity. On implantation, NovaBone Porous undergoes a time-dependent surface modification, resulting in the formation of a calcium phosphate layer on the device surfaces. The device acts as a scaffold, with new bone infiltrating the porous structure. NovaBone Porous is progressively resorbed and replaced by new bone tissue during the healing process.

5. Intended Use

NovaBone Porous is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone Porous is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides an

osteoconductive scaffold that resorbs and is replaced with bone during the healing process.

6. Technological Characteristics

The technological characteristics of the NovaBone Porous device are identical to the NovaBone Porous device as cleared per K060432, and are similar to those of the NovaBone Putty and NovaBone-AR predicates. The devices are designed as osteoconductive space-filling devices to be gently packed into defect sites and used as non-structural scaffolds for the body's natural healing and bone regeneration process. The device indications are the same as for the predicate. The device per this submission is modified to include a syringe package format to aid in material preparation and delivery.

The NovaBone Porous device is a single-phase bioactive glass (45S5 Bioglass®) device. The device implant material is unmodified from that described in K060432, with the device being in particulate form. The design modification made per this submission is to include a syringe package format to contain the device material, the syringe being similar to that for the NovaBone-AR predicate per K041613 and the NovaBone Putty predicate per K082672.

7. Warnings and Precautions

NovaBone Porous does not possess sufficient mechanical strength to support load-bearing defects prior to hard tissue ingrowth and is not indicated for use in load-bearing applications. NovaBone Porous is intended for use by clinicians familiar with bone grafting and internal/external fixation techniques. In cases of fracture fixation or where load support is required, standard internal or external stabilization techniques must be followed to obtain rigid stabilization in all planes. NovaBone Porous must not be used to gain screw purchase or to stabilize screw placement.

8. Complications

Possible complications are the same as to be expected of autogenous bone grafting procedures. These may include: superficial wound infection, deep wound infection, deep wound infection with osteomyelitis, delayed union, loss of reduction, failure of fusion, loss of bone graft, graft protrusion and / or dislodgement, and general complications that may arise from anesthesia and / or surgery.

9. Conclusion

The NovaBone Porous design modification subject to this submission is to include a filled-syringe package format to augment the current package formats. This device modification does not result in a change in technological characteristics of the device. NovaBone Porous continues to be safe and effective as a non-structural osteoconductive bone void filler for osseous defects.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NovaBone Products, LLC
% Mr. David M. Gaisser
13709 Progress Boulevard, #33
Alachua, Florida 32615

APR 15 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Re: K090731

Trade/Device Name: NovaBone Porous – Synthetic Bone Graft Scaffold
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: March 16, 2009
Received: March 19, 2009

Dear Mr. Gaisser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K090731

Device Name: NovaBone Porous – Synthetic Bone Graft Scaffold

Indications For Use:

NovaBone Porous – Synthetic Bone Graft Scaffold is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone Porous is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Prescription Use XX

OR
(Per 21 CFR 801.109)

Over-The-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K090731